Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

DATE: August 01, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Clarcon Biological Chemistry Laboratory's Seizer

SUGGESTED ACTION: **FDA Seizer; Clarcon Biological Chemical Laboratory Inc. Skin Sanitizer, Protectant Products ; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being seized were distributed in the State of Indiana. The FDA's seizure of these products, along with their ingredients and any in-process or bulk materials, occurred after Clarcon did not agree to promptly destroy them. The FDA is protecting the public by preventing these products from entering the marketplace. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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FDA NEWS RELEASE

For Immediate Release: August 1, 2009

Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

U.S. Marshals Seize Skin Sanitizer, Protectant Products Made by Clarcon Biological Chemical Laboratory Inc.

FDA acts to prevent use of Utah company's contaminated skin products

U.S. Marshals, at the request of the U.S. Food and Drug Administration, have seized all skin sanitizers and skin protectants, including ingredients and components, at Clarcon Biological Chemistry Laboratory's Roy, Utah facility. The FDA is also warning consumers not to use any Clarcon products because they contain harmful bacteria and are promoted as antimicrobial agents that claim to treat open

wounds, damaged skin, and protect against various infectious diseases. No cases have been reported to the FDA.

Clarcon voluntarily recalled the affected products, marketed under several different brand names, in June 2009, following an FDA inspection that revealed high levels of potentially disease-causing bacteria in the products.

The inspection also uncovered serious deviations from the FDA's Current Good Manufacturing Practice regulations, including poor practices that permitted the contamination. The FDA's seizure of these products, along with their ingredients and any in-process or bulk materials, occurred after Clarcon did not agree to promptly destroy them. The FDA is protecting the public by preventing these products from entering the marketplace.

"The FDA is committed to taking enforcement action against firms that do not manufacture drugs in accordance with our current good manufacturing practice requirements," said Deborah M. Autor, director of the FDA's Center for Drug Evaluation and Research Office of Compliance. "We will remain vigilant in our efforts to protect consumers from defective products."

Clarcon produced and distributed over 800,000 bottles of these products in multiple regions of the country since 2007. Consumers should not use any Clarcon products and should dispose of them in their household trash.

Analyses of several samples of the topical antimicrobial skin sanitizer and skin protectant products revealed high levels of various bacteria. Some of these bacteria can cause opportunistic infections of the skin and underlying tissues. Such infections may need medical or surgical attention and may result in permanent damage. Examples of products that should be discarded are:

Citrushield Lotion
Dermasentials DermaBarrier
Dermassentials by Clarcon Antimicrobial Hand Sanitizer
Iron Fist Barrier Hand Treatment
Skin Shield Restaurant
Skin Shield Industrial
Skin Shield Beauty Salon Lotion
Total Skin Care Beauty
Total Skin Care Work

Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, fax, or phone.
--Online
--Regular Mail: use postage-paid FDA form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
--Fax: 800-FDA-0178
--Phone: 800-FDA-1088

For more information:

Consumers Warned Not to Use Clarcon Skin Products

Photos: product labels

Facts About Current Good Manufacturing Practices (cGMPs)